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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,377

11/19/2003

Norbert L. Wiech

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EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/715,377

Applicant(s)

WIECH ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-31 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14, 19, 20 and 25 is/are rejected.
- 7) ☒ Claim(s) 15-18 and 21-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 28 December 2006.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Applicant's cancellation of claims 5 and 6 is acknowledged.
4. Claims 1-4 and 7-31 are pending.
5. The rejection under 35 USC § 112, second paragraph, set forth in paragraphs 2 and 3 of the previous Office Action mailed 2 October 2006 is withdrawn in view of Applicants' amendment.
6. The rejection under 35 USC § 112, first paragraph, set forth in paragraph 4 of the previous Office Action mailed 2 October 2006 is withdrawn upon further consideration of the rejections of record which set forth a means by which one of ordinary skill in the art could identify suitable compounds and methods for their use which clearly enable the claimed method.
7. The rejections under 35 USC § 102 set forth in paragraphs 6 of the previous Office Action in Paper No 8 is withdrawn in response to Applicants' amendment and in favor of the new rejections below.

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New Rejections and Objections
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Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4,7-14,19, 20 and 25 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Hite et al (US 5,028,629 07-1991) in view of Egan et al (American Journal of Respiratory Cell and Molecular Biology, Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoxygenase, 1993, Metabolites, 795), pages 500-506). Hite discloses (Column 28, lines 40-45 and column 29, lines 5-20) the compounds B, F and G and their *in vitro* activity as 5-lipoxygenase inhibitors. Hite further discloses (Column 2, lines 1-7) their use as anti-asthmatic compounds. Egan discloses (Page 504, column 1, lines 1-26 and column 2, Figure 4) that inhibition of the lipoxygenase pathway inhibits sodium ion transport (absorption). Cell contact occurs through the circulatory system. The instantly claimed requirement for inhibiting sodium ion transport is therefore inherently anticipated by the methods of treatment of Hite.

Examiner's Response to Applicants' Remarks With Regard to This Rejection

9. Applicants argue that Hite does not teach a method for the treatment of lung disease with a compound including an an oxyamide linkage in an amount effective to inhibit sodium ion transport. The Examiner disagrees since the disclosure of Egan demonstrates that lipoxygenase inhibitors inherently inhibit sodium ion transport.

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Applicant's arguments filed 28 December 2006 have been fully considered but they are not persuasive for the reasons indicated above.

10. Claims 1-4, 7-14, 19, 20 and 25 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Summers et al (Journal of Medicinal Chemistry, Hydroxamic Acid Inhibitors of 5-Lipoxygenase: Quantitative Structure-Activity Relationships, 1990, 33, pages 992-998) in view of Egan et al (American Journal of Respiratory Cell and Molecular Biology, Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoxygenase, 1993, Metabolites, 795), pages 500-506). Summers discloses (Page 992, Column 1, first full paragraph) the use of 5-lipoxygenase inhibitors as therapeutic agents for the treatment of asthma. Summers discloses (Page 993, column 2, Chart II) compounds which are compounds of the instantly employed formula (I). Summers discloses (Page 994, Table I, entries 39-67) the 5-Lipoxygenase inhibitory action of these compounds. Cell contact occurs through the circulatory system. Egan discloses (Page 504, column 1, lines 1-26 and column 2, Figure 4) that inhibition of the lipoxygenase pathway inhibits sodium ion transport (absorption). The instantly claimed requirement for inhibiting sodium ion transport is therefore inherently anticipated by the methods of treatment of Summers.

Examiner's Response to Applicants' Remarks With Regard to This Rejection

11. Applicants argue that Summers does not teach a method for the treatment of lung disease with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. The Examiner disagrees since the disclosure of Egan demonstrates that lipoxygenase inhibitors inherently inhibit sodium ion transport.

Applicant's arguments filed 28 December 2006 have been fully considered but they are not persuasive for the reasons indicated above.

12. Claims 1-4,7-14,19, 20 and 25 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Zusi et al (US 4,731,382 03-1988) in view of Egan et al (American Journal of Respiratory Cell and Molecular Biology, Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoyxygenase, 1993, Metabolites, 795), pages 500-506). Zusi discloses (Column 10, lines 14-19, table I, entries 6-11) compounds of formula I and their activity as inhibitors of 5-lipoyxygenase. Zusi discloses (Column 6, lines 46-64) the utility of these compounds in the treatment of asthma and COPD. Zusi discloses (Column 11, lines 41-46) the administration of these compounds by inhalation. Egan discloses (Page 504, column 1, lines 1-26 and column 2, Figure 4) that inhibition of the lipoyxygenase pathway inhibits sodium ion transport (absorption). The instantly claimed method for inhibiting sodium ion transport is therefore inherently anticipated by the methods of treatment of Zusi.

Examiner's Response to Applicants' Remarks With Regard to This Rejection

13. Applicants have presented arguments with regard to this rejection. The Examiner responds to these below:

- a. Applicants argue that Zusi does not teach a method for the treatment of lung disease with a compound including an an oxyamide linkage in an amount effective to inhibit sodium ion transport . The Examiner disagrees since Zusi teaches a method of treating lung disease with inhibitors of 5-lipoyxygenase

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and the disclosure of Egan demonstrates that lipoxygenase inhibitors inherently inhibit sodium ion transport. The instantly claimed methods are therefore inherently taught by Zusi.

- b. Applicants argue that Egan does not teach a method of inhibiting sodium ion transport in an airway epithelial cell that includes contacting the cell with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport and does not teach a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. The Examiner responds that Egan is not relied upon for such teaching.

- c. Applicants argue that, since Egan's studies on ion transport employ nordihydroguaiaretic acid which belongs to a different class of compounds than the oxyamide-containing compounds of Zusi, Egan should not be used as a secondary reference. The Examiner disagrees since the method by which Egan manipulates lipoxygenase levels is not at issue. Egan's disclosure is only employed to demonstrate the inherent relationship between lipoxygenase inhibition and sodium ion transport.

Applicant's arguments filed 28 December 2006 have been fully considered but they are not persuasive for the reasons indicated above.

Claim Objections

14. Claims 15-18, 21-24 are finally objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Claims 1-4 and 7-31 are pending. Claims 1-4, 7-14, 19, 20 and 25 are finally rejected. Claims 15-18, 21-24 are finally objected to. Claims 26-31 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


PAUL A. ZUCKER, PH.D.
PRIMARY EXAMINER
AU 1621